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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,954	11/21/2001	Peter M. Bonutti	BON-1721-11	9219
33771	7590	12/15/2004	EXAMINER	
PAUL D. BIANCO: FLEIT, KAIN, GIBBONS, GUTMAN, BONGINI, & BIANCO P.L. 601 BRICKELL KEY DRIVE, SUITE 404 MIAMI, FL 33131			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 12/15/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/988,954	BONUTTI, PETER M. <i>U</i>
	Examiner	Art Unit
	Paul B. Prebilic	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 September 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 62,69,76 and 116-139 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 62,69,76 and 116-139 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

Election/Restrictions

No claims are currently withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant elected Group II (method of using surgical implant material), species e (spacer), species 4 (biodegradable material), and Species I (fastener method) in the paper filed Applicant timely traversed the restriction (election) requirement in the reply filed on December 5, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 62, 69, 76, 116-119, 124-129, and 134 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey (US 4,890,612). Kensey anticipates the claim language where the puncture and surrounding area is the implantation site as claimed, and the expansion occurs by absorbing the liquid of blood at the implantation site; see the abstract, column 6, lines 24-51, column 7, lines 1-65 and claim 1 of Kensey. The implant is the plug (102) that is entirely within the body

With regard to claims 117 and 127, the claim language is fully met because expansion of the implant makes the implant more near more of the tissue at the site because it inherently stretches and exposes more tissue.

With regard to claims 124 and 125, the claim language is fully met because the foam is compressed before insertion and while it is being made; see column 6, lines 43-48.

Claims 62, 69, 76, 116-123, and 135-138 are rejected under 35 U.S.C. 102(e) as being anticipated by Draenert (US 5,084,050). Draenert meets the claim language where the implantation site is in bone and the sheath swells or expands when contacted with body fluids; see the abstract, column 2, lines 53-67, column 3, lines 49-58, column 4, lines 20-65, column 5, lines 12-60 and Example 1. The sheath of bone dowel is considered solid because it is not a liquid or a flowable material. Alternatively, the screw, wedge, or cylinder is considered part of the implant and making it a solid material implant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 124-134 and 139 are rejected under 35 U.S.C. 102(e) as anticipated by Draenert (US 5,084,050) or, in the alternative, under 35 U.S.C. 103(a) as obvious over

Draenert (US 5,084,050) in view of Heldermann (U S3,613,497) or Polos (US 3,874,264) or Belov et al (SU 1275136).

Draenert meets the claim language as explained in the Section 102 rejection *supra*. However, the step of compressing the implant is not explicitly disclosed therein. However, the Examiner asserts that compression of the dowel by the screw inherently takes place because the dowel is so compressed against the bone that it locks it in place; see column 3, lines 3-9. This sort of deformation of the dowel would inherently compress the structure thereof somewhat because it would not firmly lock into the bone hole otherwise.

Alternatively, one may reasonably come to the conclusion that compression of the dowel is not inherent. With this interpretation, however, Heldermann (see column 2, lines 9-29), Polos (see column 1, lines 31-56), and Belov et al (see the second paragraph of the abstract) all teach that it was known to the analogous anchor art to compress anchors as they are inserted into their respective holes as a means to prevent rotation and firmly anchor the screw later inserted therein. For this reason, the Examiner asserts that it would have been *prima fascia* obvious to insert a dowel anchor at the site of Draenert's implantation that is slightly larger than the bone hole for the same reasons that the secondary references do the same.

Response to Arguments

Applicant's arguments filed September 23, 2004 have been fully considered but they are not persuasive. In particular, Applicant argues that Kensey does not teach expansion at the wound site. The Examiner respectfully disagrees because the site is

clearly at the location of implantation in Figures 8 and 9. For example, the claims do not require that implant contact any particular tissue of the site when being expanded.

In response to the traversal of the Draenert rejection, the Examiner has modified the rejection such that it is clear that the claims are read on by Draenert.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738